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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,320	05/21/2001	Hidetoshi Uemura	UEMURA 4	6682

1444 7590 11/04/2003

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,320

Applicant(s)

UEMURA ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,20-22 and 25-57 is/are pending in the application.
- 4a) Of the above claim(s) 2,20-22, 25-29, 32-36, 43-50, 52-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,42 and 51 is/are rejected.
- 7) ☒ Claim(s) 30,31,42 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: _____

DETAILED ACTION

Applicant's response, on June 18, 2003, Paper No. 18, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have amended Claims 37-40, and 42, cancelled Claims 1, 3-19, 23, 24, and added Claims 54-57. Claims 2, 20-22, 25-57 are pending. Claims 2, 20-22, 25-29, 32-36, 43-50, and 52-57 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there being no allowable generic or linking claim. As amended, Claims 37-41 are not within the elected invention and, therefore, are also withdrawn. Claims 30, 31, 42, 51 are hereby reconsidered.

Claims-Objections

Claims 30, 31, 42, and 51 are objected to for the recitation of non-elected subject matter, i.e., polypeptides set forth by SEQ ID NO: 4 or 6 or encoded by SEQ ID NO: 3 or 5.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which, the applicant regards as his invention.

Rejection of Claim 31 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "peptide antibody" is maintained, as corrections have not been made.

Claim Rejections - 35 USC § 112-First Paragraph

Rejection of Claims 30, 31, 42, and 51 under 35 U.S.C. 112, first paragraph for lack of enablement and written description is maintained. In support of a request for withdrawal of said rejection, applicants provide the following argument. That, the present claims are amended to avoid recitation of any protein derived from residues 54-282 of SEQ ID NO: 2 by addition,

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deletion, or substitution of amino acid residues. Applicants further state, that the present claims, as amended, satisfy the written description requirements because the hybridization language is similar to the language used in Example 9 (Hybridization) of the Revised Interim Written Description Guidelines Training Materials. These arguments are not found to be persuasive for the following reasons.

Claim 42(b) presently recites a protein encoded by a nucleotide, which is hybridizable to a nucleotide complementary to the nucleotide sequence of SEQ ID NO: 1. As described below, the hybridization conditions for Claim 42 are indefinite; see rejection of Claim 42 under 35 USC § 112-Second Paragraph. Claim 42 does not recite the hybridization conditions described in Example 9, page 74, lines 13-18; furthermore, said conditions, hybridization in 5xSSC, at 65°C, without SDS, is not considered to be high stringency conditions (Maniatis et al, 1982). Claim 42(b) continues to recites an extremely large genus of proteins that encompasses polypeptides derived from SEQ ID NO: 2, as well as polypeptides derived from residues 54-282 of SEQ ID NO: 2, by addition, deletion, or substitution of amino acid residues. Claim 42(m) presently recites a modified derivative or fragment of a protein consisting of residues 54-282 of SEQ ID NO: 2, as well as a modified derivative or fragment of 42(b). Thus, Claim 42(m) also recites a very large genus of proteins that encompasses polypeptides derived from SEQ ID NO: 2, as well as polypeptides derived from residues 54-282 of SEQ ID NO: 2, by addition, deletion, or substitution of amino acid residues. Thus, one of skill in the art would not be enabled by the specification, without undue experimentation, to make and use the proteins encompassed by the genera of polypeptides recited by Claim 42. Claims 30, 31, and 51 are rejected for the same reasons, as they are dependent on Claim 42.

Claim Rejections - 35 USC § 102

Rejection of Claim 42 under 35 U.S.C. 102(b) as being anticipated by Marra et al, 1996 and under 35 U.S.C. 102(e) as being anticipated by Cohen et al, 2001 (US Pat# 6232456; Filing Date October 6, 1997), for the reasons described in the prior action, are maintained. In support of a request for withdrawal of said rejection, applicants argue that the nucleotide sequence encoding the serine proteases of Marra et al and Cohen et al would not hybridize to the nucleotide sequences encoding the presently recited protein embodiments under the stringent conditions defined on page 25, line 22 to page 26, line 13 of the specification. This argument is not is not found to be persuasive. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. The hybridization conditions described on pages page 25, line 22 to page 26, line 13 of the specification are only exemplary and, furthermore, do not define high stringency conditions; see Maniatis et al, 1982.

NEW ISSUES***Claims-Objections***

Claims 30, 31, 42, and 51 are objected to for the following reasons.

Claim 42 is objected to for twice reciting the phrase "...having a nucleotide sequence represented by nucleotides 272" on lines 2-4. Claim 42 is also objected to for the phrase "the protein (a)" on line 12. Said phrase should be changed to "the protein in (a)". Claims 30, 31, and 51 are objected to for the same reasons, as they are dependent on Claim 42.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 30, 31, 42, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Claim 42 is indefinite in the recitation of "hybridizable...under stringent conditions" as this term is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. The hybridization conditions described on page 25, line 22 to page 26, line 13 and page 74, lines 13-18 of the specification are only exemplary and do not define the conditions recited in Claim 42. Thus, Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Since, Claims 30, 31, and 51 are dependent on Claim 42, said claims are also rejected for the reasons described for Claim 42.

Claim 42 recites the limitation "the serine protease activity" on lines 5-6 and the limitation "the same serine protease activity" on lines 11-12. There is insufficient antecedent basis for this limitation in the claim. Therefore, Claim 42 is indefinite. Since, Claims 30, 31, and 51 are dependent on Claim 42, said claims are also rejected for the reasons described for Claim 42.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al, 1996.

Marra et al teach a serine protease protein having 91% identity with residues 116-270 of SEQ ID NO: 2. Since Claim 42(m) recites modified derivatives or fragments of the protein consisting of residues 54 to 282 of SEQ ID NO: 2, Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al, 1996.

Claim 42 is rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al, 2001 (US Pat# 6232456; Filing Date October 6, 1997) or Southan et al, 2000 (US Pat# 6100059; Filing date April 8, 1998). Cohen et al teach a serine protease protein that has 97% identity with residues 54-282 of SEQ ID NO: 2. Southan et al teach a serine protease protein that has 54% identity with residues 77-278 of SEQ ID NO: 2. Since Claim 42(m) recites modified derivatives or fragments of the protein consisting of residues 54 to 282 of SEQ ID NO: 2, Claim 42 is rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al, 2001 or Southan et al, 2000 (US Pat# 6100059; Filing date April 8, 1998).

Claims 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al, 2001, since Cohen et al teach antibodies to their protein (col 4, lines 55-61). Prior rejection of Claims 30 and 31 under 35 U.S.C 102(b) over Yoshida et al is withdrawn. In support of a request for withdrawal of said prior rejection, applicants provided the following argument, which is relevant to the rejection here of Claims 30 and 31 under 35 U.S.C. 102(e), as being anticipated by Cohen et al. That Yoshida et al (now rejection over Cohen et al) does not disclose the mature protein and, accordingly, applicants do not believe that Yoshida's (now Cohen's) protein will have the same conformation and the same epitopes to raise the presently claimed antibody. This

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argument is not found to be persuasive for the following reasons. Claims 30 and 31 do not limit the scope of the claimed antibodies to those that would recognize the native conformation of the protein set forth by SEQ ID NO: 2. Furthermore, the protein of Cohen et al comprises the complete polypeptide set forth by SEQ ID NO: 2. Since 91% of the protein of Cohen et al is the polypeptide of SEQ ID NO: 2, a person of ordinary skill in the art would predict the conformation of the protein taught by Cohen et al would be very similar to the polypeptide of SEQ ID NO: 2 and that the majority of antibodies generated using the protein of Cohen would cross react with the polypeptide set forth by SEQ ID NO: 2.

Claim 51 is rejected under 35 U.S.C. 102(e) as being anticipated by Southan et al, 2000 (US Pat# 6100059; Filing date April 8, 1998). Southan et al teach a pharmaceutical comprising their polypeptide (col 16, lines 57-60), which is a modified variant of SEQ ID NO: 2 herein, as described above. Therefore, Claim 51 is rejected under 35 U.S.C. 102(e) as being anticipated by Southan et al, 2000.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
10/17/2009
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